DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

95154d

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Stoneham, Massachusetts 02180
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WARNING LETTER

NWE-31-04W

VIA FEDERAL EXPRESS

July 19, 2004

Mr. Peter J. Sacchetti
President/Owner
OST Medical,Inc.
11 Knight Street, Building F23
Warwick, RI 02886-1281

Dear Mr. Sacchetti:

We are writing to you because on February 24-26, March 2-4, and March 10, 2004, the Food and Drug Administration (FDA) conducted an inspection of your Warwick, Rhode Island, facility which revealed serious regulatory problems involving your Sentinel Enteral feeding pumps, which were made for you and marketed by your firm.

Under a United States law, the Federal Food, Drug and Cosmetic Act, this product is considered to be a medical device because it is used to diagnose or treat a medical condition. Moreover, your activities, including specification development for the Sentinel Enteral feeding pumps, make you a manufacturer under the law. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country. The law also requires that device manufacturers comply with certain requirements for relying on recognized standards and for the design and manufacture of medical devices.

Although you received premarket clearance via a letter, dated June 1, 2001, the above inspection revealed that the device you are currently marketing is not the device described in the premarket notification (510(k)) [redacted] submitted (K011587). When significant changes are made to a cleared device, a new 510(k) is required. You redesigned the original device [redacted] You should have submitted

another premarket notification submission for this change, in accordance with section 510(k) of the Act and Title 21, Code of Federal Regulations (CFR), Section 807.81(a)(3)(i).

Because you do not have marketing clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification that shows your device is substantially equivalent to other devices that are legally marketed. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device, your product is also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

It is important to understand, too, that if you make a significant change in the future production of your device, a new 510(k) will be needed for that change as well.

The kind of information you need to submit in order to obtain this clearance is described on FDA's device web site at www.fda.gov/cdrh/devadvice. FDA will evaluate this information and decide whether your product may be legally marketed.

The above-stated inspection also revealed other problems with your device. In particular, your cleared 510(k) contained a statement that the device conforms with UL544, a recognized standard, but you have not performed testing on the Sentinel Enteral Feeding Pump to show conformance with this standard. Under section 501(e)(2), a device is adulterated if it is declared to be in conformity with a recognized standard but is not in all respects in conformity with the standard.

In addition, the inspection found that your devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in 21 CFR, Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to perform design changes according to approved established procedure as required by 21 CFR 820.30(i). Specifically, there is no written procedure for the upgrade from software version [redacted] to [redacted]

2. Failure to establish a design and development plan as required by 21 CFR 820.30(b). Specifically, there was no design plan for the Sentinel Enteral Feeding Pump. Although the contract manufacturer produced approximately [redacted] pumps between May and November 2001, a design and development plan had not been established at the time of manufacture of these pumps.

3. Failure to establish and maintain procedures to ensure that the device design

was correctly translated into production specifications as required by 21 CFR 820.30(h). Specifically, the design transfer procedures were not established until November 4, 2002, which was after the production of over [redacted] pumps.

4. Failure to perform design validation under defined operating conditions on initial production units, lots, or batches, or their equivalents as required by 21 CFR 820.30(g). Specifically, final product testing was performed on a different device from the one cleared under K011587 without demonstrating that the device was the equivalent of initial production units. In addition, with no documentation to show that the three pumps used for the validation of Version [redacted] had been upgraded from Version [redacted], there is no assurance that the validation for Version [redacted] was conducted with pumps which actually contained Version [redacted] software.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We acknowledge the receipt of your letter dated April 20, 2004 which responded to the FDA 483 that was issued to your facility on March 10, 2004. We acknowledge the correction of most items, however, you should respond to the above items with adequate detail to demonstrate that you are taking appropriate corrective actions to prevent the recurrence of these serious violations in the future.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

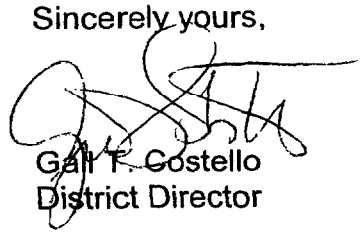
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Current Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at www.fda.gov/cderh/dsma/dsmastaf.html.

You may wish to contact the Recall Coordinator, Susan Liner, in FDA's New England District Office at 781-596-7750 to discuss the product in commercial distribution.

It is necessary to take action on this matter now. Please let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response or any questions you may have to Karen Archdeacon, Compliance officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. Her telephone number is (781) 596-7707; FAX No. 781-596-7899.

Sincerely yours,



Gail T. Costello
District Director